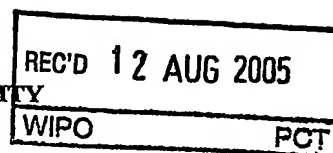


# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 48919-00003	FOR FURTHER ACTION		See Form PCT/IPEA/416																
International application No. PCT/US04/21038	International filing date (day/month/year) 30 June 2004 (30.06.2004)	Priority date (day/month/year) 01 July 2003 (01.07.2003)																	
International Patent Classification (IPC) or national classification and IPC IPC(7): A61F 13/00 and US Cl.: 424/400, 464, 434, 435, 439																			
Applicant MAIBACH, TODD																			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table style="margin-left: 20px; border: none;"> <tr><td><input checked="" type="checkbox"/> Box No. I</td><td>Basis of the report</td></tr> <tr><td><input type="checkbox"/> Box No. II</td><td>Priority</td></tr> <tr><td><input type="checkbox"/> Box No. III</td><td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td></tr> <tr><td><input type="checkbox"/> Box No. IV</td><td>Lack of unity of invention</td></tr> <tr><td><input checked="" type="checkbox"/> Box No. V</td><td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td></tr> <tr><td><input type="checkbox"/> Box No. VI</td><td>Certain documents cited</td></tr> <tr><td><input type="checkbox"/> Box No. VII</td><td>Certain defects in the international application</td></tr> <tr><td><input type="checkbox"/> Box No. VIII</td><td>Certain observations on the international application</td></tr> </table>				<input checked="" type="checkbox"/> Box No. I	Basis of the report	<input type="checkbox"/> Box No. II	Priority	<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/> Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/> Box No. VI	Certain documents cited	<input type="checkbox"/> Box No. VII	Certain defects in the international application	<input type="checkbox"/> Box No. VIII	Certain observations on the international application
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<input type="checkbox"/> Box No. VIII	Certain observations on the international application																		
Date of submission of the demand 01 February 2005 (01.02.2005)		Date of completion of this report 15 July 2005 (15.07.2005)																	
Name and mailing address of the IPEA/ US. Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer: <i>Lakshmi S. Channavajjala</i> Lakshmi S. Channavajjala Telephone No. (571) 272-1600																	

Form PCT/IPEA/409 (cover sheet)(January 2004)

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/21038

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☒ the international application as originally filed/furnished
- ☒ the description:
- pages 1-31 as originally filed/furnished
- pages\* NONE received by this Authority on \_\_\_\_\_
- pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the claims:
- pages 32-48 as originally filed/furnished
- pages\* NONE as amended (together with any statement) under Article 19
- pages\* NONE received by this Authority on \_\_\_\_\_
- pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the drawings:
- pages NONE as originally filed/furnished
- pages\* NONE received by this Authority on \_\_\_\_\_
- pages\* NONE received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☒ The amendments have resulted in the cancellation of:
- ☒ the description, pages NONE
  - ☒ the claims, Nos. NONE
  - ☒ the drawings, sheets/figs NONE
  - ☒ the sequence listing (*specify*): NONE
  - ☒ any table(s) related to the sequence listing (*specify*): NONE
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(e)).
- ☐ the description, pages \_\_\_\_\_
  - ☐ the claims, Nos. \_\_\_\_\_
  - ☐ the drawings, sheets/figs \_\_\_\_\_
  - ☐ the sequence listing (*specify*): \_\_\_\_\_
  - ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/US04/21038**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>3-6, 8-53, 58-104</u>	YES
	Claims <u>1, 2, 7, 54-57</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-104</u>	NO
Industrial Applicability (IA)	Claims <u>1-104</u>	YES
	Claims <u>NONE</u>	NO

**2. Citations and Explanations (Rule 70.7)**  
Please See Continuation Sheet

## Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Claims 1, 2, 7 and 54-57 lack novelty under PCT Article 33(2) as being anticipated by JP 58213709 (JP).

JP discloses an agent capable of being kept in the oral cavity for a long time absorbing a drug in the gum effectively. The agent is obtained by laminating a composition containing a water-soluble or water-swellaable polymer and a film-forming agent such as cellulose or its derivatives, polyvinyl alcohol or polyvinylpyrrolidone. JP discloses incorporating nitroglycerin as a drug in the film and also teaches incorporating any other drug for remedy purposes. The ability to not adhere is inherent in the film of JP. Thus, instant claims do not meet the step of novelty.

Claims 8-50 and 64-71 lack an inventive step under PCT Article 33(3) as being obvious over JP 58213709 (JP).

JP fails to teach the percentage of the film forming agent, nitroglycerin and also fails to specify each and every drug of the instant claims. However, JP suggests that the mucosal agent for oral cavity can be used to incorporate any drug as a preventive or as a remedy for various diseases. JP also fails to teach the specific step of drying the drug and the film-forming polymer after casting on a substrate. However, JP teaches laminating the drug and polymer on a substrate and accordingly depending on the dryness desired, adding a drying step would have been obvious for a skilled artisan. Further, adding a desired pharmaceutical agent that can be orally administered, as a drug in the film-forming agent JP so as to provide prevention or a remedy would have been within the scope of a skilled artisan.

Claims 3-6, 51-53, 58-63 and 72-104 lack an inventive step under PCT Article 33(3) as being obvious over JP 58213709 (JP) in view of WO 01/7109.

JP does not teach pullulan as the film forming agent or the claimed surfactants, sweeteners, flavoring agents, surfactants, etc. of instant claims.

WO teaches a fast dissolving orally consumable edible film containing a drug, a taste-masking agent, flavoring agents, surfactants, etc., the film forming material being a pullulan. WO teaches including a number additives in the film including, surfactants, sweeteners etc (pages 3 and 9-15), any known pharmaceutically active agent (pages 4-6) other film-forming agents such as cellulose equivalent to

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/US04/21038

Supplemental Box

pullulan (pages 6-9). Therefore, it would have been obvious for one of ordinary skill in the art at the time of the instant invention to use pullulan as a film-former in the nitroglycerin-containing agent of JP and still expect the same drug absorption through the oral mucosal cavity. Further, it is also obvious to add any of the drugs and additives such as sweeteners, taught by WO, in the composition of JP depending on the desired pharmacological and additive effect.

Claims 1-104 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.